

Attorney Docket No.: DEX-0180  
Inventors: Roberto A. Macina  
Serial No.: 09/806,302  
Filing Date: July 19, 2001  
Page 2

#### REMARKS

Claims 1 and 11-20 are pending in the instant application.

Rejections under 35 U.S.C. 112, first paragraph and 35 U.S.C. 102(e) have been withdrawn.

Claims 1, 11, 12, 15, 18 and 21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Lehrer (US Patent Application No. 2002/0034739) in view of either Ni (U.S. Patent 6,066,724) or Gentz (WO 97/34997). The Examiner suggests that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a method for the detection of the polynucleotide of Ni or Gentz in the methods of Lehrer to detect uterine or ovarian cancer metastasis in a bodily fluid because Lehrer teaches methods for detection of metastasis of uterine or ovarian cancer by measurement of polynucleotide encoding ESPBIII, and because the sequence of SEQ ID NO:1 was provided by Ni or Gentz prior to the filing date of this application.

Applicants respectfully traverse this rejection.

In accordance with MPEP § 2143 to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the

Attorney Docket No.: DEX-0180  
Inventors: Roberto A. Macina  
Serial No.: 09/806,302  
Filing Date: July 19, 2001  
Page 3

reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. The cited combination of prior art references fails to meet these basic criteria.

Claims of the instant application are drawn to a method for detecting the presence of uterine or ovarian cancer in a patient which comprises measuring levels of ESBPIII comprising a polynucleotide sequence of SEQ ID NO:1 in cells tissues or bodily fluids in a patient and comparing the measured levels of ESBPIII with levels of ESBPIII in cells, tissues or bodily fluids from a normal human control. It is specifically stated in the claims that an increase in measured levels of ESBPIII in the patient versus normal human control is associated with the presence of uterine or ovarian cancer.

In contrast, the only expression data presented in Lehrer relates to prostate cancer. Further, Lehrer teaches that decreased lipophilin C expression at less than 50% of normal was shown in 76.9% of the samples and that 4 of the 10 samples with diminished lipophilin expression also had greatly diminished expression of lipophilin B. See Example 8 and in particular paragraph [0075] at page 6 of Lehrer. The data presented in Lehrer is thus unrelated to methods for detecting ovarian or uterine cancer and actually teaches

Attorney Docket No.: DEX-0180  
Inventors: Roberto A. Macina  
Serial No.: 09/806,302  
Filing Date: July 19, 2001  
Page 4

away from a method for detecting cancer wherein an **increase** in expression of ESBPIII is indicative of the cancer.

Thus, this reference provides neither a reasonable expectation of success with respect to the instant claimed invention wherein an increase in expression is indicative of uterine or ovarian cancer nor a teaching or suggestion of this claim limitation.

Secondary references of Ni and Gentz, which are silent with respect to methods for detecting uterine or ovarian cancer, fail to remedy the deficiencies in the teachings of the primary reference of Lehrer.

Further, step (c) of claim 1 requires a comparison step to levels in normal controls. However, claimed methodologies of Lehrer are all based on mere presence of the complex being indicative of tumor metastases. No comparison step is taught or suggested by Lehrer.

Again, secondary references of Ni and Gentz fail to remedy the deficiencies in the teachings of the primary reference of Lehrer.

Thus, since the cited combination of prior art fails to provide any reasonable expectation of success with respect to a method for detecting the presence of uterine or ovarian cancer based on detecting an increase in ESBPIII levels as compared to normal human controls and fails to provide the requisite teaching or suggestion of all the limitations of

Attorney Docket No.: DEX-0180  
Inventors: Roberto A. Macina  
Serial No.: 09/806,302  
Filing Date: July 19, 2001  
Page 5

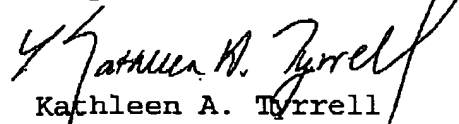
the claimed invention, this combination of references cannot render obvious the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

#### Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

Date: March 2, 2005

LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515